

REMARKS

Claims 1 – 8, 10, 11 and 13 – 16 are pending in this application.

Claims 8 – 17 have been rejected.

Claims 1 – 7 have been withdrawn due to a prior restriction requirement and timely election with traverse.

Claims 9, 12 and 17 have been canceled.

Claims 8 and 13 have been amended.

Claim Objections

The objection to claim 9 has been rendered moot by the cancellation of the claim.

Amendments to the Claims

Claims 8 and 13 have been amended to incorporate the requirements of canceled dependent claims 12 and 17, respectively. Claims 8 and 13 now require a stylet that stretches the catheter so that the diameter of the stylet is decreased to eighty-five percent or less of its relaxed diameter. This change is supported by the prior claims. No new matter has been added.

Claims 9, 12 and 17 have been canceled.

Rejections Under 35 USC § 102

Claims 8, 10, 11, 13, 15 and 16 have been rejected under 35 USC § 102(e) as being anticipated by U.S. Patent Application No. 2002/0107506 (“McGuckin, Jr. et al. ‘506”). These rejections are respectfully traversed.

McGuckin, Jr. et al ‘506 discloses a dialysis catheter that may be stretched via a stiffening rod in order to facilitate insertion (paragraph [140]). The stiffening rod is inserted into the proximate end of the catheter and slid down so the distal end of the stiffening rod is pressed against the distal end of the catheter (paragraph [141]). The proximal end of the catheter is then stretched to bring a first threaded connector on the catheter into contact with a second threaded connector on the stiffening rod and the stiffening rod is torqued to fasten the

connectors together (paragraph [141]). The effect is to stretch the catheter, thereby reducing the diameter of the catheter “from about 0.215 millimeters to about 0.207 millimeters” (see paragraph [141]). In other words, the diameter in the stretched catheter is reduced to about 96% ($0.207/0.215 = 0.9628$) of the diameter of the catheter in its relaxed state.

By contrast, claims 8 and 13, as amended, require “a second attachment affixed a fixed distance away from said distal end of said stylet ... said fixed distance is selected to reduce said predetermined diameter of said catheter in said stretched state to eighty-five percent (85%) or less of said predetermined diameter of said catheter in said relaxed state.” This difference is significant. Claims 8 and 13 require a percentage decrease in diameter nearly four times greater than that disclosed by McGuckin, Jr. et al ‘506. A percentage decrease in diameter by 15% requires structures in the stylet (and the catheter) that are far more robust than what are required to reduce the diameter by a mere 4%.

Furthermore, McGuckin, Jr. et al ‘506 has no apparent motivation to decrease the diameter of the catheter by more than 4%, as the catheter disclosed in McGuckin, Jr. et al ‘506 is for use in dialysis, which essentially amounts to wending the catheter through the blood vessels. McGuckin, Jr. et al ‘506 does not show, disclose or suggest that a reduced diameter is essential to the process or even that it is more than an incidental benefit derived from securely fastening the catheter to the stylet. McGuckin, Jr. et al ‘506 does not teach a use for which a percentage reduction of the diameter of a catheter by 15% or more is needed.

By contrast, the stylet of the present invention is to be used with a catheter inserted in a hole in the dura of smaller diameter than the diameter of the relaxed state of the catheter, thereby allowing the catheter to expand, once implanted, and form a secure seal in the hole in the dura so as to reduce seepage of cerebrospinal fluid between the catheter and the edge of the hole, thereby avoiding potentially serious side effects (specification paragraph [10]). McGuckin, Jr. et al ‘506 had no motivation to avoid such side effects, which is why McGuckin, Jr. et al ‘506 was satisfied with a reduction in diameter of just four percent. By contrast, by allowing a reduction of at least 15%, the present invention allows for a tight seal between the dura and the catheter, thereby reducing side effects. Indeed, McGuckin, Jr. et al ‘506 teaches away from the ability to reduce the diameter by more than four percent by

stating so precisely the diameter of the catheter in the relaxed state compared with the diameter in the stretched state.

Thus, McGuckin, Jr. et al '506 does not show, disclose or suggest reducing the diameter of the catheter by 15% or more. It is respectfully submitted that the rejection of claims 8 and 13, as amended, is improper and should be withdrawn.

Claims 10 and 11 are dependent on claim 8 and claims 15 and 16 are dependent on claim 13 and thus are subject to all of the limitations of the claims on which they depend. Thus, because the rejections of claims 8 and 13 are improper, it is respectfully submitted that the rejections of claims 10, 11, 15 and 16 are also improper and should be withdrawn.

Rejections Under 35 USC § 103

Claims 9, 12, 14 and 17 have been rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin, Jr. et al '506. These rejections are respectfully traversed.

With respect to claim 14 and as discussed above, McGuckin, Jr. et al '506 discloses a dialysis catheter that may be stretched via a stiffening rod in order to facilitate insertion (paragraph [140]). The stiffening rod is inserted into the proximate end of the catheter and slid down so the distal end of the stiffening rod is pressed against the distal end of the catheter (paragraph [141]). The proximal end of the catheter is then stretched to bring a first threaded connector on the catheter into contact with a second threaded connector on the stiffening rod and the stiffening rod is torqued to fasten the connectors together (paragraph [141]). The effect is to stretch the catheter, thereby reducing the diameter of the catheter "from about 0.215 millimeters to about 0.207 millimeters" (paragraph [141]). However, McGuckin, Jr. et al '506 does not show, disclose or suggest reducing the diameter of the catheter by 15% or more.

As discussed above, for this reason the rejection of claims 8 and 13 is improper. Claim 14 is dependent on claim 13. Because McGuckin, Jr. et al '506 does not show, disclose or suggest all of the elements of claim 13, claim 14 cannot be obvious in light of McGuckin, Jr. et al '506. Thus, it is respectfully submitted that the rejection of claim 14 is improper and should be withdrawn.

The rejection of claims 9, 12 and 17 is rendered moot by the cancellation of those claims.


Summary

In view of the amendments made and the arguments presented, claims 1 – 17 should be allowable, this application should be in condition for allowance and a notice to that is earnestly solicited.

Respectfully Submitted,

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